

REMARKS

This Amendment responds to the non-final Office Action dated August 11, 2008 (the Office Action). Claims 1-5, 11, 20-22, 24, 25, 37-40 and 73-76 are pending. By this Amendment, claims 6-10, 12-19, 23, 26-36 and 41-72 are cancelled, claims 1, 74 and 75 are amended and new claim 77 is added.

Amendments

Claim 1 was amended

- (i) to claim the irregularly shaped pieces, e.g., as at page 8 lines 12-15;

“In accordance with the present invention one or more rods, plugs, crushed or irregularly shaped pieces of substantially dehydrated hydrogel material are introduced into a lumen or void in a patient’s body to seal or plug a biopsy needle track, serve to reinforce weak tissue, or deliver a therapeutic compound”.

- (ii) to claim the pellets, e.g., as at page 22 lines 1-6:

“Upon delivery to the vascular network, the hydrogel articles, which may be in rod, pellet, fiber, rolled up film or other physical form, rehydrate and occlude the vascular flow by mechanical obstruction.”

- (iii) to claim the beads, e.g., as at page 13 lines 16-20:

“The surface to volume ratio of the implanted hydrogels also is expected to have an impact on the rate of swelling. For example, crushed dried hydrogel beads are expected to swell faster to the equilibrium water content state than a rod shaped implant of comparable volume.

- (iv) to claim direct administration through the needle, e.g., as at page 17 lines 6-7:

“A preformed plug of a hydrogel selected as described hereinabove may be placed in a needle track, for example, using the same device that was used for the tissue retrieval.”

- (v) to claim direct administration through the catheter, e.g., as at page 21 line 5 to page 22 line 5, emphases added:

“Hydrogel articles of the present invention may be introduced into a patient’s body in a low profile, substantially dehydrated state, such that upon hydration the hydrogel article occludes an abnormal vascular structure. . . . Embolization typically is accomplished using low-profile soft microcatheters that allow superselective catheterization into the brain to deliver an embolic material under fluoroscopic guidance. . . . In accordance with the principles of the present invention, substantially dry hydrogel materials may be introduced with a catheter under radiographic guidance to embolize AVMs.”

Claims 74 and 75 and new claim 77

Claims 74 and 75 and new claim 77 were amended or added to claim the shapes claimed in claim 1.

Rejection

Claims 1-5, 11, 20-22, 24, 25, 37-40 and 73-76 have been rejected under 35 U.S.C. §112 ¶1 for lack of written description. The Office Action reviews example 12 and original claim 53 for support but concludes that the disclosure is limited to a rod without guidance for the other shapes of sphere, block, sheet, or tube. Secondly, the

Office Action concludes that while a rod of 1.5 mm diameter is disclosed, this disclosure does not equate to passing it through a tube with an inner diameter of no more than 1.5 mm as claimed. While the Office Action acknowledges original claim 53 discloses hydrogels shaped for passage through an inner diameter of a catheter or hollow needle into the body, it expresses the concern that the rod, block, sheet or tubes are not thereby disclosed as passing into the body and also does not find that the inner diameter of the catheter or needle is no more than 1.5 mm. Finally, the Office Action finds that the examined claims lacked a limitation to having a shape for direct administration through a catheter or hollow needle into the body.

The written description requirement under the first paragraph of 35 U.S.C. §112 requires that the disclosure of the invention in the originally filed application reasonably convey to one having ordinary skill in the art that the inventor had in his possession the later claimed subject matter as of the filing date of the application. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

In brief, the Application discusses introducing dehydrated hydrogels through a tissue biopsy needle. Tissue biopsy needles commonly are needles with inner diameters of less than about 1.5 mm. Accordingly, the artisan must understand that application possessed introducing dehydrated hydrogels through needles with inner diameters of 1.5 mm.

The Office Action itself points to claiming a shape that provides for direct administration through a catheter or hollow needle into the body. The claimed limitation of being able to pass through a catheter or needle with a specified maximum outer

diameter (“no more than about 1.5 mm”) is intended to provide clarity and definiteness to the shape that is claimed.

Specifically, publications describing tissue biopsy needles are attached, along with a guide to gauge sizes. These publications describe a wide variety of biopsy needles that have an inner dimension of less than about 1.5 mm. These all describe many needles with a “gauge” with a number higher than 14 that have an inner diameter of less than about 1.5 mm.

Original claim 63, dependent on claim 53 discussed by the Office Action, specifies that “wherein the lumen or void is created by a biopsy procedure”. Accordingly, Applicant possessed passing the hydrogel through a tool into the body with an inner diameter of less than 1.5 mm because biopsy tools repeatedly mentioned in the Application commonly had such diameters. The specification also provides support, e.g.:

(vi) Page 7 lines 14-17:

It is a further object of the present invention to provide methods of using and
15 forming hydrogel articles for plugging voids created in tissue during surgical procedures, such as
a needle track created during a biopsy, so as to reduce the risk of hemorrhage after tissue
removal.

(vii) Page 8 lines 12-15

In accordance with the present invention one or more rods, plugs, crushed or
irregularly shaped pieces of substantially dehydrated hydrogel material are introduced into a
lumen or void in a patient’s body to seal or plug a biopsy needle track, serve to reinforce weak
tissue, or deliver a therapeutic compound. The hydrogel polymer preferably rehydrates rapidly,

(viii) Page 17 lines 1-6

1. Sealing of Biopsy Tracks

Biopsy needle tracks may be embolized in accordance with the principles of the present invention to reduce complications associated with needle biopsies, such as bleeding and airleaks. A preformed plug of a hydrogel selected as described hereinabove may be placed in a needle track, for example, using the same device that was used for the tissue retrieval.

Accordingly, since the hydrogel may be administered by and through, among other places, a biopsy needle (the same device used for the tissue retrieval as at item (viii)), it is respectfully submitted that there is written description for placement of hydrogels through the catheter or needle with an inner diameter of no more than about 1.5 mm as claimed. Item (v), above, further emphasizes delivery through a low-profile (i.e., small diameter) catheter.

The Office Action's only other concerns are believed to be related to support for shapes other than rods. The present claims find explicit support for the pellet, bead, and irregularly shaped pieces as described for the amendment of claim 1. The limitation of a sheet rolled from one edge to another to form a roll is also clearly supported in the specification, e.g., as at item (ii) above ("a rolled up film) or at Example 6 (a "carpet roll").

Item (ii) above indicates broad possession of more than just rod-shapes because it discusses "rods", "plugs", and "irregularly" shaped items. Further disclosure is provided of rods, pellet, fiber, rolled-up film, or other physical form in a "low-profile" shape for delivery through the vasculature to treat arteriovenous malformations:

(v) Page 21 lines 5-8 and Page 22 lines 1-6.

Continuation

Please note that a continuing application, Serial No. 11/406,791 has received a first action on the merits as of August 14, 2008. An Information Disclosure Statement will be provided to submit that office action.

Conclusion

Allowance of the claims is respectfully requested. Please contact the undersigned if it would be helpful to resolve any further concerns.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

Respectfully submitted,

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